PHP110
REVIEW AND COMPARISON OF DIFFERENT NATIONAL GUIDELINES ON THE IMPLEMENTATION OF NETWORK META-ANALYSIS
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OBJECTIVES: For an evaluation of a treatment to be truly useful, it should be compared to the other treatments that may be used in the patient group under consideration. Randomised controlled trials are a key source of evidence for these comparisons. The techniques of indirect comparisons and network meta-analysis allow the complete network of trial evidence to be evaluated in order to obtain estimates of comparative efficacy. These techniques may be the only source of estimates of comparative effectiveness if trials directly comparing the treatments of interest have not been conducted and may provide useful additional evidence if both direct and indirect comparisons exist. **METHODS:** We examined both published and draft guidelines from reimbursement and health technology appraisal bodies, and considered their recommendations using appropriate methodology for the conduct of indirect comparisons and the assessments of their validity. **RESULTS:** The following countries were studied; Australia, Canada, France, Germany, Korea, Sweden, and USA, with particular emphasis on the differences and similarities in these guidelines with each other, and with the guidelines established by the Cochrane collaboration. **CONCLUSIONS:** Finally, we present an example analysis demonstrating how the various requirements could be met in practice.

PHP111
GLOBAL EVIDENCE GENERATION - CHALLENGES FOR THE PHARMA INDUSTRY
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Health technology assessments around the world are changing at a pace that it is becoming extremely difficult for the pharmaceutical companies to keep up to the demands of health authorities around the world. Market access, commercial and more specifically clinical development teams are facing a mamoth task of developing and generating clinical data in a form that will satisfy the increasing expectations of health care systems around the world. **OBJECTIVES:** This research paper analysis the current trends in data expectations from key markets around the world. This specific objective was to develop a matrix that will identify the differences and commonalities in clinical data expectations in selected key markets of US, France, Germany, UK, The Netherlands, Spain, Italy, Poland, China, Australia, Turkey, India, Brazil and Mexico. **METHODS:** A combination of ndepth secondary research followed by interviews with key stakeholders in each market was used to achieve the objectives of the project. Clinical experts who are involved in clinical trial design in key research centres, payers at the national and regional level and executives from pharmaceutical industry were interviewed. **RESULTS:** It was concluded that there is huge variance in data expectations in the selected markets and for this reason countries could be placed in different buckets. For instance, some countries focus on economic assessment (UK, Australia) while other focus on well designed RCTs against relevant comparator (Germany, France). The 2011 introduction of AMNOG has resulted in deadlock between the manufacturers and the GBA (Joint federal committee) in Germany on the choice of comparator. Similarly the new clinical guidelines that are being introduced in China require data with local/Chinese population. The French Transparency (TC) commission is not considering drugs as valuable (AMSR scoring) if they are not supported with a well designed comparator study. The paper elaborates on such global challenges.

PHP112
INVESTMENT AND DISINVESTMENT OF HEALTH TECHNOLOGIES: THE NEED FOR TWO COST-EFFECTIVENESS THRESHOLDS
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OBJECTIVES: The concept of a cost-effectiveness "threshold" has been adopted either explicitly or implicitly by health care decision makers in numerous jurisdictions. This paper demonstrates that, under very weak assumptions – applicable to all realworld health systems – decision makers ought to instead adopt two cost-effectiveness thresholds. **METHODS:** A simple model of a hypothetical health care system is used to demonstrate the appropriate threshold(s) under various assumptions concerning: 1) the size of the health care budget; 2) the extent to which technology, productivity and/or input prices change over time; 3) whether the amount of information available to decision makers changes over time; and 4) the fixity of the set of adopted health care technologies in the short term. **RESULTS:** The assumptions which must hold for two thresholds to be appropriate are that: 1) there is some fixity in the set of adopted health care technologies in the short term, and 2) either 1) technology, productivity and/or input prices change over time, or 2) the information available to decision makers changes over time, or both. Where these assumptions hold, one threshold ought to be used when appraising technologies with positive incremental costs (investment decisions), while a different threshold should be used when appraising technologies with negative incremental costs (disinvestment decisions). This is true regardless of the marginality of the technologies under consideration. **CONCLUSIONS:** This finding has profound implications for the practice of cost-effectiveness analysis, for ongoing and future empirical research into the nature of the threshold, and for health care policy making. It gives a theoretical underpinning to observations that the ICERs of technologies disinvested at the margin differ from those of technologies adopted at the margin. It also has implications for the interpretation of ICERs, for the appropriate calculation of net benefit, and for the conduct of value of information analysis.

DISEASE-SPECIFIC STUDIES

MUSCULAR-SKELETAL DISORDERS – Clinical Outcomes Studies

PMS1
DEMOGRAPHIC AND CLINICAL CHARACTERISTICS OF DULOXETINE PATIENTS WITH CHRONIC LOWER BACK PAIN OR OSTEOARTHRITIS IN 2011
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OBJECTIVES: Identify and compare demographic and clinical characteristics of patients diagnosed with osteoarthritis (OA) or chronic lower back pain (CLBP) who initiated treatment on duloxetine after FDA approval of its use for management of chronic musculoskeletal pain late in 2010. **METHODS:** Commercial patients 18-64 years of age who initiated duloxetine treatment between January 1, 2011 and July 30, 2011 were identified in the IMS Longitudinal Prescription and Medical Claims Database. The index event was defined as the first duloxetine prescription fill with no duloxetine pill-coverage for 90 days prior. Patients were assigned to disease-category cohorts on the basis of ICD-9 codes on medical claims dated within -180/+7 days of the index event. χ^2-tests were used to compare differences across study cohorts. Additional cohorts based on other FDA approved duloxetine indications and for the same time period a year prior to the primary study period were constructed for comparison. **RESULTS:** A total of 422,911 duloxetine initiators with >1 of duloxetine's six approved indications were identified in the IMS database, of which 80,637 had either CLBP (42,280) or OA (38,357) as the only diagnosed condition from among the six. OA patients were older than CLBP patients (60.6 vs. 52.1 years; $p<0.001$). An almost equal proportion of OA and CLBP patients (47%) were treated by primary care physicians. CLBP patients were more likely prescribed an anticonvulsant (52.7% vs 37.3%; $p<0.001$) or an opioid (93.5% vs. 84.1%; $p<.001$) than were OA patients. OA patients were more likely to have been previously diagnosed with a non-CLBP related musculoskeletal pain condition. OA patients were more likely to initiate duloxetine treatment at sub-therapeutic (<40 mg/day) dosing levels than CLBP patients (32.1% vs. 26.8%; $p<0.001$). Results for 2011 were little changed from 2010 results. **CONCLUSIONS:** Overall, patient profiles among duloxetine initiators with CLBP displayed modest differentiation relative to patients with OA in 2011.

PMS2
THE EFFICACY OF DULOXETINE, NON-STEROIDAL ANTI-INFLAMMATORY DRUGS, AND OPIOIDS IN OSTEOARTHRITIS: A META-ANALYSIS
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OBJECTIVES: Comparative evidence evaluating the efficacy of oral osteoarthritis treatments has frequently included short-term trials. Meta-analyses of longer-term trials are needed. This meta-analysis of trials 12 weeks or longer was conducted to assess the efficacy of duloxetine vs. other oral treatments recommended after the use of acetaminophen for osteoarthritis, including non-steroidal anti-inflammatory drugs (NSAIDs) and opioids. **METHODS:** Search strategy: A systematic literature review was performed in PUBMED, EMBASE, MedLine In-Process, Cochrane Library, and ClinicalTrials.gov up to September 2011. Randomized controlled trials (RCTs) of duloxetine and all oral NSAIDs and opioids were included if the duration of treatment was twelve weeks or longer, the Western Ontario and McMaster Universities Index (WOMAC) total score was available, and they were published in English. Data collection and analysis: The WOMAC baseline and change from baseline total scores were collected and standardized. Twelve additional study characteristics were collected and study quality was assessed. A frequentist meta-analysis and indirect comparison were performed using the DerSimonian-Laird and Bucher methods. Bayesian analyses with and without study-level covariates were performed using noninformative priors. **RESULTS:** A search of the literature identified 24 studies which met inclusion criteria. The frequentist analysis and the Bayesian analysis without covariates found no statistically significant difference between the efficacy of duloxetine and the other treatments. Meta-regression suggested baseline scores explain much of the variance in change from baseline scores. The results, however, adjusted for study-level covariates led to the same conclusion. **CONCLUSIONS:** This analysis suggests that the efficacy of duloxetine in osteoarthritis, as measured by the WOMAC total score at 12 weeks or longer, is similar to competitor drugs.

PMS3
COMPARATIVE EFFECTIVENESS ANALYSIS USING "REAL-WORLD" PATIENT DATABASE TO EVALUATE THE FRACTURES RATES COMPARING ANNUAL ZOLEDRONIC ACID INFUSION WITH ORAL BISPHOSPHONATES
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OBJECTIVES: This study evaluated clinical fracture rates before and after two years of zoledronic acid infusion (ZOL) or oral bisphosphonate (OBP) initiation using a large national claims data set. **METHODS:** Patients ≥45 years with at least one claim of ZOL or OBP were extracted from Thomson Reuters MarketScan® Databases January 1, 2006-October 31, 2010. Index date was the date of the first ZOL or OBP claim. Each patient had ≥1 diagnosis of osteoporosis prior to index date. All patients had at least two-year continuous enrollment prior to (pre-period) and two-year continuous enrollment post (follow-up period) index date. Patients with any ZOL use during the study period were excluded from the OBP cohort. Differ-